510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA I990 and 21 CFR §807.92.

The assigned 510(k) number is:K130516.

1. **Submitter's Identification:**

GETEMED Medizin- und Informationstechnik AG
Oderstrasse 77, 14513 Teltow, Germany
Tel: + 49 - 3328 3942 0

AUG 2 3 2013

Contact: Dr. Bert Schadow
Regulatory Affairs Manager
GETEMED Medizin- und Informationstechnik AG
Oderstrasse 77, 14513 Teltow, GERMANY
Tel: + 49 – 3328 3942 70
Fax: + 49 – 3328 3942 99

Date Summary Prepared: February 22, 2013

2. **Name of the Device:** CardioDay®

3. **Device Class:** Class II

4. **Common or Usual Name:** Holter evaluation software

5. **Predicate Device Information:**

Device	Manufacturer	510(k) Number
CardioDay® 2.0	GETEMED Medizin- und Informationstechnik AG	K070280

6. **Device Description:**

CardioDay® is a software package that allows a trained physician or health care professional knowledgeable in Holter interpretation, after having performed a long-term continuous electrocardiographic (ECG) recording on digital flash memory Holter recorder, to download and analyze the data from the recorder, review it and produce printed reports. CardioDay® does not perform any diagnosis of data by itself but only displays ECG morphologies and associated, calculated graphs such as heart rate trends, RR variability, and other statistical values in graphical form. The physician will be able to review, edit, and print the data collected.

7. Intended Use:

CardioDay® is a software package that allows you, a trained physician or health care professional knowledgeable in Holter interpretation, after having performed a long-term continuous electrocardiographic (ECG) recording on digital flash memory Holter recorder, to download and analyze the data from the recorder, review it and produce printed reports.
This device is available only upon the order of a physician or other licensed medical professional and not intended for any ambulatory or home applications.

United States federal law restricts CardioDay® to sale by or on the order of a physician.

8. Comparison to Predicate Devices:

The Holter evalution software CardioDay® 2.4 is substantially equivalent to CardioDay® 2.0 (K070280) from GETEMED Medizin- und Informationstechnik AG. There have been no changes implemented in the modifications to CardioDay® 2.4 that impact either the fundamental technology or the indications for use. Some incremental changes were made in the workflow and in the naming of menu entries to improve the usability, to support more Holter ECG recorders and to bring the technical details up-to date. A TWA (T-Wave Alternance) algorithm was implemented that is identical to an already FDA approved TWA algorithm (510(k)# K032513).

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Non-clinical testing that has been conducted includes:
a. ECG performance testing according to AAMI / ANSI / EC 38;
b. Software development life cycle according to AAMI / ANSI / IEC 62304

None of the testing demonstrated that CardioDay® 2.4 brought up any issues of safety or effectiveness.

10. Discussion of Clinical Tests Performed:

No clinical testing was performed in order to support safety or effectiveness.

11. Conclusion:

CardioDay® version 2.4 is identical to its predicate device in intended use, indications for use and operating principle. Some incremental changes were made in the workflow to identify artefacts in the ECG recording. To improve the usability some menus are relabeled. Some more Holter ECG recorders are supported. A TWA (T-Wave Alternance) algorithm was implemented that is identical to an already FDA approved TWA algorithm (510(k) # K032513).

Verification and validation of CardioDay 2.4 demonstrated that these small differences do not raise any new questions of safety and effectiveness to the subject device and the subject device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 23, 2013

Getemed Medizin – Und Informationstechnik Ag
C/O Dr. Bert Schadow
Oderstr. 77
Teltow, Brandenburg
Germany 14513

Re: K130516
Trade/Device Name: CardioDay version 2.4
Regulation Number: 21 CFR 870.1425
Regulation Name: Holter ECG Evaluation Software
Regulatory Class: Class II
Product Code: DQK
Dated: July 9, 2013
Received: July 10, 2013

Dear Dr. Schadow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K130516

Device Name: CardioDay® 2.4

Indications For Use:

CardioDay® is a Holter software which is indicated for patients who may benefit from a long-term continuous electrocardiographic (ECG) recording, including, but not limited to, those with complaints of palpitations, syncope, chest pain, shortness of breath, or those that need to be monitored to judge their current cardiac functionality such as patients who have recently received pacemakers.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Owen P. Faris -S
Date: 2013.08.23
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